

HEINE mini-c hand-held examination light



DATA	
Description	Examination light
Catalogue number	D-008.73.109
Date	March 4, 2021

MECHANICAL	
Weight product	22 g
Weight battery	23 g
Weight packing including product	110 g
Dimensions product	20 x 118 [mm]
Dimensions packaging	190 x 65 x 45 [mm]
Imprints	Instrument: HEINE, product name, DMC, MD, CE, www.heine.com, LOT number

ELECTRICAL	
Power supply	2x 1.5 V alkaline primary battery
Power consumption	max. 250 mW
Operating time	typ. 12 h
Safety class	internally powered

OPTICAL	
Type	HEINE LED illumination (HQ)
Illuminance	typ. 4 000 lx in 100 mm distance
Colour temperature	typ. 4 000 K
Color rendering index (CRI)	typ. > 90
Medium life expectancy (LED)	> 60 000 h
Working distance	50 to 100 mm
Classification according to IEC 62471	Group 2
Optical safety according to ISO 15004-2	Group 2

GENERAL	
Material	Plastic, metal
REACH/RoHS	Conform
Phthalate	Contains no phthalate
Latex	Contains no latex
Biocompatibility	Conform
Surface	Plastic ,chrome plated brass
Environmental conditions operation	+10 °C to +35 °C, 30 % to 75 % rel. humidity, 700 hPa to 1060 hPa
Environmental conditions storage	+5 °C to +45 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa
Environmental conditions transport	-20 °C to +50 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa
Instructions for use	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues *
Operating elements	power on switch
Removable parts/ accessories	LED head
Maintenance	Battery change
Service	Device is service-free
Patents	N/a

*) further languages on request



HYGIENIC REPROCESSING

Procedure	Housing can be cleaned and disinfected manually (wipe clean and wipe disinfect). Please see detailed description in the users manual
------------------	--

CODES

GTIN	4053755198535
Customs code (tariff number)	90189084
Country of origin	DE
Traceability	LOT number

REGULATORY

Product classification (EU)	Class I
Product classification (USA)	Class I, 510(k) exempt
Product classification (Canada)	n/a
UMDNS code	12-276
GMDNS code	36843
Regulation number (FDA)	880.6350
Product code (FDA)	KYT

Fulfills the Requirements of Directives & Standards

ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
Directive 93/42/EEC	European directive for medical devices
IEC 60601-1	Medical electrical equipment: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
ISO 14971	Medical devices - Application of risk management to medical devices
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
DIN EN ISO 15004-2	Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection
ANSI Z80.36	Ophthalmics - Light Hazard Protection for Ophthalmic Instruments
IEC 60601-1-9	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
ISO 17664	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
DIN EN 1041	Information supplied by the manufacturer of medical devices
DIN EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 2248	Packaging, complete, filled transport packages; vertical impact test by dropping
Directive (2011/65/EU) ROHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive (2012/19/EU) WEEE	Waste of electrical and electronic equipment
Regulation (1907/2006) REACH	Registration, evaluation, authorization and restriction of chemicals

